



MedDRA Training Services

PSI INTERNATIONAL, Inc. (PSI), a Fairfax, Virginia-based company, was initially established in 1977 to provide Information Technology (IT) services. Since that time, we have effectively expanded our capabilities and subject matter expertise to include the areas of Health Science, Social Services, and other technical disciplines. Over the years we have developed and maintained an impressive resource pool of professionals which has earned the respect of our global client community.

PSI's Health Science practice provides a broad base of services to our government and global commercial clients. PSI supports various phases of a new drug development life cycle:

- ◆ PSI's experienced scientists and clinicians facilitate clinical research by offering expert advice in the planning, coordination, and monitoring of all facets of clinical trial initiatives
- ◆ Through our support of the Food and Drug Administration (FDA) and the National Cancer Institute's Cancer Therapy Evaluation Program, PSI has gained an in-depth understanding of the best means to achieve and maintain operational compliance with the published policies and guidance of the FDA, including 21 CFR Part 11
- ◆ We are thoroughly adept at navigating the regulatory process, including developing and processing Investigational New Drug Applications, Adverse Event Reports, Annual Reports, Investigator's

Brochures, and various legal agreements.

PSI's premier Drug Safety Support Services, *DS³*, is within our Health Science practice and includes:

- ◆ Data Entry and Data Entry Quality Control (QC)
- ◆ Safety Review including Coding, Coding QC, and Narrative Writing
- ◆ Aggregate Reporting
- ◆ Medical Review
- ◆ Scientific Writing
- ◆ Training
- ◆ Risk Management Services
- ◆ Information Technology.

PSI's *DS³* is available at the client site or at PSI provided facilities. We offer full outsourcing of corporate functions, such as adverse event processing services as well as assistance in supporting specific activities, such as coding files on a "one time basis" or routine support over an extended period of time.

PSI's MedDRA Training is Comprehensive

PSI provides the most comprehensive MedDRA Training Services available today. Our training is based on over 10 years of corporate support in the regulatory and commercial client environments on four continents.

PSI has provided training to over 50 Pharmaceutical and Biotech Companies and Contract Research Organizations in MedDRA, WHO-DD and Drug Safety functions. We have trained over 4,000 students including:

- ◆ Medical Monitors
- ◆ Coders
- ◆ Data Managers
- ◆ Clinical Associates
- ◆ Drug Safety Associates
- ◆ Statisticians
- ◆ Analysts
- ◆ Data Entry Specialists.

In addition to standard PSI developed classroom training, training is available on request at the customer site anywhere in the world and on a periodic basis at select cities throughout the U.S. PSI offers customized training that allows the client to define the depth of knowledge desired of their trainees.

All classroom training is developed by PSI MedDRA professionals who have an extensive history of providing MedDRA services to our clients, thus, leveraging numerous years of lessons learned in the development of courses. Trainers are PSI Certified MedDRA professionals who have supported our global clients in the regulatory and commercial arena. They are Drug Safety professionals who have supported PSI clients for at least three years, and most have worked together at PSI for over five years. PSI sets such standards for trainers because many of our students are Drug Safety professionals who require interaction during the training process that can only be satisfied by trainers who are medical professionals possessing practical subject matter skills.

In addition to classroom training, PSI provides workshops intended for advanced MedDRA students who are interested in exploring concepts that can only be appreciated by those who possess significant MedDRA experience.

PSI offers consulting to clients in the development of their training program and assists them in creating in-house MedDRA training courses which are commonly integrated into the organization's overall corporate training program. We also provide "train-the-trainers" and ongoing support to maintain the program on a long term basis.

PSI's full suite of MedDRA Training is available today to assist you in maximizing your overall MedDRA investment.

For more information about our MedDRA services, visit our web site at www.MedDRAHelp.com or contact:

Bill York
Director, Business Development
PSI INTERNATIONAL, Inc.
4000 Legato Road, Suite 850
Fairfax, Virginia 22033-4055
Office: (703) 621-5834
Fax: (703) 352-8236
[**byork@psiint.com**](mailto:byork@psiint.com)